NOTIFICATION G/SPS/N/USA/933
Use of Materials Derived from Cattle in Human Food and Cosmetics
- Interim Final Rule -
[Docket No. 2004N–0081]

COMMENTS BY ARGENTINA

1 - RULE DESCRIPTION

The interim final rule issued by the Food and Drug Administration (FDA) prohibits the use of certain cattle material, to address the potential risk of bovine spongiform encephalopathy (BSE) in human food, including dietary supplements, and cosmetics.

Prohibited cattle materials include specified risk materials, small intestine of all cattle, material from non-ambulatory disabled cattle, material from cattle not inspected and passed for human consumption, and mechanically separated (MS)(Beef).

Specified risk materials are the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia of cattle 30 months and older; and the tonsils and distal ileum of the small intestine of all cattle. Prohibited cattle materials do not include tallow that contains no more than 0.15 percent hexane-insoluble impurities and tallow derivatives.

FDA is taking this action in response to the finding of an adult cow, imported from Canada, that tested positive for BSE in the State of Washington.

This action is consistent with the recent interim final rule [1] issued in January by the US Department of Agriculture (USDA), on the prohibition of the use of specified risk materials in human food and requirements for the disposition of the non-ambulatory disabled cattle. In the USDA rule, specified risk materials and the carcasses and parts of non-ambulatory disabled cattle are declared to be inedible, unfit for human food, their use as human food is prohibited and it is required that the entire small intestine be removed and disposed of as inedible.

2 - SPS AGREEMENT

In its **Article 3.1**, the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) provides for the Members' obligation to base their sanitary and phytosanitary measures on international standards, guidelines or recommendations, where they exist.

Notwithstanding this, **Article 3.3** recognizes the Members' right to introduce or maintain measures which result in a higher level of protection than would be achieved by measures based on the relevant international standards, guidelines or recommendations - assumptions that will have to be based on scientific evidence.

[1] NOTIFICATION G/SPS/N/USA/844 - Interim final rule - Docket No. 03-025IF.

In turn, under **Article 6.1**, "Members shall ensure that their sanitary or phytosanitary measures are adapted to the sanitary or phytosanitary characteristics of the area from which the product originated and to which the product is destined."

3- BSE: ARGENTINA'S SANITARY STATUS

On June 21 2004, the OIE submitted before the WTO the document **G/SPS/GEN/501**: Issues of Interest to the SPS Committee Discussed by the OIE International Committee at the 72nd General Session - *Communication from World Organization for Animal Health (OIE).*

There, it is informed the adoption of, *inter alia*, Resolution No. XXI relative to the "Bovine Spongiform Encephalopathy Status of Member Countries". Thereunder, Argentina is one of the four countries so far officially recognized by said international organization as "provisionally free from BSE" in accordance with the provisions of Article 2.3.13.4 of the Terrestrial Code.

4- TERRESTRIAL ANIMAL HEALTH CODE **(Basado en versión en inglés del 07/09/04, que figura en la página de la OIE)**

The Terrestrial Code sets out BSE-related provisions on trade that make distinctions by product, or by their origin country or zone. Article 2.3.13.18 also refers to their purpose, establishing that:

1. From cattle of any age originating from a **country or zone with a moderate or a high BSE risk**, the following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilizers, cosmetics, pharmaceuticals including biologicals, or medical devices: tonsils and intestine, and protein products derived thereof. Food, feed, fertilizers, cosmetics, pharmaceuticals or medical devices prepared using these commodities should also not be traded

2. From cattle originating from a **country or zone with a moderate or a high BSE risk**, that were at the time of slaughter over 12 months of age, the following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilizers, cosmetics, pharmaceuticals including biologicals, or medical devices: brains, eyes, spinal cord, skull and vertebral column and protein products derived thereof. Food, feed, fertilizers, cosmetics, pharmaceuticals or medical devices prepared using these commodities should also not be traded.

3. From cattle originating from a **country or zone with a minimal BSE risk**, that were at the time of slaughter over 30 months of age, the following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilizers, cosmetics, pharmaceuticals including biologicals, or medical devices: brains, eyes and spinal cord, skull, vertebral column and derived protein products. Food, feed, fertilizers, cosmetics, pharmaceuticals or medical devices prepared using these commodities should also not be traded.

Thus, it is possible to note that there are no determinants established for imports from BSE provisionally free countries, Argentina's officially-recognized sanitary status.

5- ARGENTINA'S COMMENTS

A) Comments on the Form

From a procedural standpoint, Argentina's comments to this measure are the same as those duly submitted in relation to the interim final rule notified as G/SPS/N/USA/844 - Prohibition of the use of specified risk materials in human food and requirements for the disposition of the nonambulatory disabled cattle.

In that sense, the procedure implemented by the US in order to notify the measure under analysis has not followed the rules of the procedure recommended to apply the transparency-related obligations set out in the SPS Agreement (Article 7) [2] since

- the measure was not notified before becoming effective as its application is immediate and binding for any country wishing to export the products included therein to the US, and
- neither does it correspond to any of the causes that justify the application of an urgency measure since this is not a case where the US faces problems of urgent sanitary protection or a threat thereof.

B) Comments on the Substance

Argentina shares with the US the concern resulting from the BSE case occurred in the state of Washington. However, we disagree on the criterion of immediate and binding application of the notified rule to all countries.

The fact that the sanitary status of exporting countries is not considered in the rule (Art. 6 - SPSA) leads to the indiscriminate restriction of the entry of products posing different risk levels.

Ignoring the sanitary status of the country or zone of origin of the products must not be deemed as a minor issue when, in addition to the SPS Agreement provision, there is a qualification range in the Terrestrial Animal Health Code ranking from country or zone free from BSE, country or zone provisionally free from BSE, country or zone with a minimal BSE risk, country or zone with a moderate BSE risk, to country or zone with a high BSE risk. That is, there are five categories of sanitary status and Argentina enjoys the top one of those so far recognized.

In Argentina's case,

- both cattle brains and spinal cords are used for human consumption, but since 2002 their use for animal feeding has been prohibited as an additional risk mitigation measure;
- the BSE-related ineffectiveness of the distal ileum is associated with the lymphoreticular tissue, and it has been detected only in bovines that have been experimentally infected;

[2] G/SPS/7/Rev2

- since 10/01/2000, in the entire European Union, it is mandatory to withdraw from the human and animal food chains the specified risk materials like the spinal cord, brains, eyes, tonsils and part of the intestines from cattle; however, under the circular letter E3D(03) 532459/jfp dated on October 9 2003 in Brussels, the EU accepts the entire small intestine from Argentina;
- the non-ambulatory cattle that, in being inspected by professionals, prove to be so due to evidently traumatic causes are not involved in the epidemiological surveillance program implemented in Argentina and are used for human consumption.

6- PETITION BY ARGENTINA

Bearing in mind these considerations, Argentina thanks for the chance to submit comments and requires the United States to make the pertinent modifications to the notified text in order for the notified entry restrictions to be adjusted to the sanitary status of the exporting countries, as set out in the IOE Terrestrial Animal Health Code.

Such modifications may be made by excluding from the application scope of the rule the materials from cattle born and raised in a country free or provisionally free from BSE as recognized by the IOE, or by acknowledging the equivalence of the measures implemented by those countries to those notified by the US on the mitigation of BSE exposure risks.